

We, Mölnlycke Health Care AB, Gamlestadvägen 3C, Box 13080, SE-402 52 Göteborg, Sweden being exclusively responsible manufacturer for conformity of the device/s; declare that the devices listed in the attached schedule are in conformity with the provisions of the Council Directive 93/42/EEC of 14 June 1993, as amended by 2007/47/EEC, concerning medical devices, the Medical Devices Act SFS 1993:584 and the Swedish Medical Product Agency regulations and guidelines: Medical Devices, LVFS 2003:11, as amended by LVFS 2009:18.

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|--------------------------------------|-----------------|
| Trade name/ Product name: | Exufiber |
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Product classification: IIb

Sterility Status: Sterile

Measuring function: No

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|---|-----------|
| This declaration is supported by a conformity assessment procedure in accordance with | |
| Annex/es: | II |

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|----------------------------|-----------------|
| Certificate number: | CE 01965 |
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|-------------------|-------------------|
| Issued by: | BSI (2797) |
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For non sterile, non-measuring Class I products, no certificate is issued by a Notified Body.

Mölnlycke Health Care issues this declaration in recognition of all applicable harmonised standards.

Signed for and on behalf of Mölnlycke Health AB Care

Date: 2021-04-27

Function: Regulatory Affairs Manager
Compliance

Name: Karin Darle Olsson

Signature:



Product(s) covered by this declaration:

| Product Reference: | Product Descriptor: | GMDN Code: |
|---------------------------|----------------------------|--|
| 709900 | Gelling fibre dressing | 43186 Exudate - absorbent dressing, hydrophilic-gel, sterile |
| 709901 | Gelling fibre dressing | 43186 Exudate - absorbent dressing, hydrophilic-gel, sterile |
| 709902 | Gelling fibre dressing | 43186 Exudate - absorbent dressing, hydrophilic-gel, sterile |
| 709903 | Gelling fibre dressing | 43186 Exudate - absorbent dressing, hydrophilic-gel, sterile |
| 709904 | Gelling fibre dressing | 43186 Exudate - absorbent dressing, hydrophilic-gel, sterile |
| 709905 | Gelling fibre dressing | 43186 Exudate - absorbent dressing, hydrophilic-gel, sterile |
| 709906 | Gelling fibre dressing | 43186 Exudate - absorbent dressing, hydrophilic-gel, sterile |
| 709907 | Gelling fibre dressing | 43186 Exudate - absorbent dressing, hydrophilic-gel, sterile |
| 709908 | Gelling fibre dressing | 43186 Exudate - absorbent dressing, hydrophilic-gel, sterile |

| Product Reference: | Product Descriptor: | GMDN Code: |
|---------------------------|----------------------------|--|
| 709909 | Gelling fibre dressing | 43186 Exudate - absorbent dressing, hydrophilic-gel, sterile |
| 709912 | Gelling fibre dressing | 43186 Exudate - absorbent dressing, hydrophilic-gel, sterile |
| 709913 | Gelling fibre dressing | 43186 Exudate - absorbent dressing, hydrophilic-gel, sterile |
| 709914 | Gelling fibre dressing | 43186 Exudate - absorbent dressing, hydrophilic-gel, sterile |
| 709915 | Gelling fibre dressing | 43186 Exudate - absorbent dressing, hydrophilic-gel, sterile |
| 709916 | Gelling fibre dressing | 43186 Exudate - absorbent dressing, hydrophilic-gel, sterile |
| 709917 | Gelling fibre dressing | 43186 Exudate - absorbent dressing, hydrophilic-gel, sterile |
| 709918 | Gelling fibre dressing | 43186 Exudate - absorbent dressing, hydrophilic-gel, sterile |
| 709919 | Gelling fibre dressing | 43186 Exudate - absorbent dressing, hydrophilic-gel, sterile |